How to Cite:
Ismael, A. E. F. A., Hafez, A. E. A. A. A. E., & Hassan, M. H. M. (2022). Assessment of endovenous microwave catheter ablation in the treatment of primary lower limb varicose veins. *International Journal of Health Sciences*, *6*(S6), 4311–4319.
https://doi.org/10.53730/ijhs.v6nS6.11602

Assessment of endovenous microwave catheter ablation in the treatment of primary lower limb varicose veins

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Abstract---Background: Lower limbs varicose veins are common in the adult population, The CEAP classification is a conventional way of staging varicose vein disease.Traditional treatment is surgery, which involves disconnection of sapheno-femoral and/or sapheno-opopliteal junctions with or without stripping of the superficial axial vein. the endovenous ablation is now the most widely used procedure and approximately occlusion rate of 95%. the Endovenous ablation techniques is Endovenous Microwave Ablation (EMA) which works by generating radio-frequency energy. It generates radiofrequency energy with the MICROTAZE OT-110 M machine. Aim: The aim of this study is using endovenous microwave ablation as a new technique in treatment of lower limb varicose veins according to the results, advantages, disadvantages and complications. Subjects and Methods: This study was conducted on 30 patients with varicose veins of lower limbs. It was conducted in the department of vascular surgery, Al-Azhar University Hospitals – Cairo (Al-Hussein and and said-Galal Hospitals). After taking a written consent, patients were subjected to Clinical evaluation and Duplex Ultrasound. Results: over weighted and patients with 30-50 years were the most .A statistically significant improvement was observed in AVVQ at different follow-up intervals. Conclusion: This prospective, single-center study found endovenous microwave ablation of the great saphenous vein to be safe and effective. Minimal complications, no DVT or paresthesia, modest post-procedural pain, and good radiological and clinical mid-term findings.

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.
Manuscript submitted: 9 April 2022, Manuscript revised: 18 June 2022, Accepted for publication: 27 July 2022

Keywords---endovenous, microwave, catheter, varicose veins, lower limbs.

Introduction

Lower limbs varicose veins are common in the adult population, which are considered the most common vascular diseases and affect up to one-third of the population in the developed countries, affecting the quality of life of patients (Evans et al., 2015). Women are more susceptible than men; other risk factors include advancing age, pregnancy, prolonged standing and obesity. Incompetent valves in the venous system cause a reduction in the returning blood from the legs which in turn predispose for the development of dilated and tortuous veins from the leg to the thigh causes primarily cosmetic worries (Lohr et al., 2013). Symptoms not only include pain but also itching, burning discomfort, heaviness, swelling, postural cramps, night cramps, cosmetically disfiguring and further it may lead thrombophlebitis or ulcer formation which generally is difficult to heal. The CEAP classification (Clinical severity, Etiology or cause, Anatomy and Pathophysiology) is a conventional way of staging varicose vein disease. The clinical severity classification spans from C0; representing no visible skin change, to C5/C6 with healed or active leg ulcers (Marsden, 2013).

Traditional treatment is surgery, which involves disconnection of sapheno-femoral and/or sapheno-popliteal junctions with or without stripping of the superficial axial vein. Surgery is usually performed under general or spinal anesthesia. It requires hospitalization, associated with wound- related complications and phenomenon of neovascularization / recurrence as a result of groin dissection increasing the risks of bleeding, paresthesia, infection, scarring, increased hospital costs and prolonged recovery (González Cañas et al., 2021). More attentions was paid on the development of minimally invasive alternatives to replace of surgical treatment. Among these, the endovenous ablation is now the most widely used procedure and approximately occlusion rate of 95% could be achieved by introducing a specific catheter into the blood vessel lumen to produce endothelial and vein wall damage with subsequent fibrosis which has been proved to be less invasive than conventional surgery due to lower complication rate and more tolerance. (Kavithal and Rajeswari, 2021).

One of the Endovenous ablation techniques is Endovenous Microwave Ablation (EMA) which works by generating radio-frequency energy with the MICROTAZE OT-110 M machine. In a randomized controlled trial comparing conventional surgery to EMA for the treatment of great saphenous vein incompetence. Inner lining of veins is damaged to induce local inflammation and fibrosis. This leads to vein occlusion and abolishes the superficial reflux. EMA was shown to be efficacious with 97% vein occlusion rate, with no recurrence (Wang et al., 2020). Complications of Endovenous ablation included the following: deep vein thrombosis, pulmonary embolism, pain syndrome, abscess, seroma, hyperpigmentation, and burn of the skin (Mao and Zhang, 2019).

Patients and Methods

This prospective randomized controlled study was conducted in the vascular surgery department at Al- Azhar University Hospitals – Cairo (Al-Hussein and and sayed-Galal), in the period from Jan 2022 to July 2022 (6 months). The study included 30 patients, males were 12 (40%) while females were 18(60%), presented with primary varicose veins of the lower limbs. All patients had symptomatic varicose veins with documented GSV incompetence and were classified according to the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification. The severity and extent of GSV reflux were evaluated preoperatively with duplex scanning. Reflux in the great saphenous vein (GSV) and deep (femoral vein andpopliteal vein) venous systems were assessed with patients in the standing position. Presence of incompetent perforators was not routinely evaluated.

Inclusion criteria

Patients with primary uncomplicated lower limbs varicose veins, age from 18 to 55 years old, incompetent great saphenous vein and sapheno-femoral junction, intact deep venous system, vein diameter at the GSV ≥5.5 mm and ≤15 mm, reflux in GSV >0.5 second on duplex study, CEAP classification between C2 and C5.

Exclusion criteria

Patients with past history of deep venous thrombosis, patients with recurrent varicose veins, GSV diameter ≥ 15 mm, patients with contraindications or allergy to anesthesia, pregnant women with varicose vein, patients refuse to be included in the study and patients with Connective tissue disorders or inflammation skin disorder in puncturing area.

Patient evaluation

Clinical evaluation and Duplex Ultrasound. Clinical evaluation was carried out for all patients according to the following scheme: Detailed history (disfigurement, pain, bleeding, deep venous thrombosis, drug allergy, anticoagulant therapy,.....). Detailed general examinations, local examination of the lower limbs to detect: Distribution of veins affected, incompetent perforators and shape (spider, serpentine or saccular)

Statistics

Data collected and maintained regarding to : age, gender, right or left lower limb or bilateral .

Pre- procedure Assessment

CBC, coagulation profile, liver and kidney function tests, viral markers and Doppler/duplex scan for all patients.

Preoperative duplex scanning

Duplex scanning will be performed to document the patency of the deep veins and to evaluate the extent and severity of the reflux in the superficial venous system (GSV and SFJ) of patients.

The procedure

Performed with the patient under local tumescent anesthesia

Position: in supine position.

Sterilisation

Sterilization of the affected limb with bovidon iodine then putting of sterilized towels.

Postoperative

Early discharge out of hospital (approx. 2 hours after the ablation, Compression by medical stocking above knee grade 2 from 2_4 weeks, diosmine tab twice daily for 4 weeks and anti-inflammatory drugs was advised for 3 days.

Every patient was advised to

Avoid straining; strenuous physical activity or Valsalva maneuvers for the first month because they may contribute to early recanalization. Avoid prolonged car or plane travel of more than 4 hours during the first month after treatment to decrease the incidence of the thromboembolic events.

Follow up of patients

Patients will be evaluated and followed up immediately, during a week and after month up to 6 months clinically and duplex u/s scanning for occurrence of complications or recurrence.

Ethical considerations

Written consent was taken from all patients before including them in the study. Aims of the study and any possible risk were discussed with all patients. Privacy of the collected data is assured. Investigations were delivered to patients. Follow up of the patients will is done after the procedure.

Results

A total of 30 patients diagnosed with primary lower limb varicose veins undergoing endovenous microwave ablation, were enrolled in our study. Table 1 demonstrated basic CERAP classification data of enrolled patients.

Table 1
Patient CERAP Characteristics (N = 30)

	Value
CEAP	
C2	7 (23.3%)
C4	10 (30.3%)
C5	10 (30.3%)
C5	3 (10%)

CEAP: clinical, etiological, anatomical, and pathophysiological.

By ultrasonographic examination (Table 2), the mean diameter of GSV was 7.82 ± 1.56 mm (range, 6 – 15). The mean reflux time was 2.8 ± 1.04 seconds (range, 0.7 – 4). Twenty-one (70%) patients had two or less perforators, while nine (30%) patients had more than two perforators.

Table 2
U/S Characteristics (N = 30)

	Value
Diameter of GSV (mm)	7.82 ± 1.56
Reflux Time of GSV (seconds)	2.8 ± 1.04
Number of Perforators	
> 2 per limb	9 (30%)
≤ 2 per limb	21 (70%)

GSV: great saphenous vein.

As demonstrated in Table 3, the mean procedure time was 40.5 ± 14.6 minutes (range, 30 – 50). The power was adjusted at 50 watts. The mean time for ambulation postoperatively was 2.4 ± 1.8 hours, ranging from 2 to 3 hours. The mean duration for hospital stay was 0.5 ± 0.35 days (range, 0.5 – 1). The mean postoperative VAS for pain was 2 ± 1.3 (range, 1 – 4). The mean time for ulcer healing was 3.67 ± 1.3 weeks, ranging from 2 to 5 weeks.

Table 3
Surgical Outcomes (N = 30)

	Value
Procedure Time (minutes)	40.5 ± 14.6
Power for GSV (watt)	50
Time to Ambulation (hours)	2.4 ± 1.8
Length of Hospital Stay (days)	.5 ± 0.35
VAS for Pain	2.0 ± 1.3
Time to Ulcer Heal (weeks)	3.67 ± 1.3

Table 4 illustrates preintervention values of venous clinical severity score (VCSS) and Aberdeen varicose vein questionnaire (AVVQ) and follow-up values at 1 and 6 months.

Table 4
Clinical Assessment (N = 30)

	VCSS	AVVQ
Preintervention	5.6 ± 1.3	18.5 ± 4.3
1 month follow-up	2.1 ± 0.6	8.1 ± 2.4
6 months follow-up	1.2 ± 0.3	4.5 ± 1.2
P value [a]	.013	.020
P value [b]	.000	.000
P value [c]	.000	.000
P value [d]	.041	.005

[a] Repeated measure ANOVA
[b] Post-hoc test preintervention vs 1 month
[c] Post-hoc test preintervention vs 6 months
[d] Post-hoc test 1 month vs 6 months

Table (5): shows that GSV diameter was ranged between 4.50 – 9.50 with a mean value of 6.52±1.271 and it was decreased significantly at postoperative time to reach after 6 months of follow up to be at mean value 0.52±0.252.

GSV Diameter	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
Min – Max	4.50 – 9.50	3.20 – 8.50	1.30 – 6.40	0.60 – 4.30	0.10 – 0.90
Mean ± S.D	6.52±1.271	5.31±1.273	3.50±1.070	1.88±0.731	0.52±0.252

Table 6 summarizes the reported complications in our series. Six (20%) patients developed induration, four (13.3%) patients had ecchymosis, three (10%) patients had accidental skin burns, and none developed infection at the incision site. One patient (3.3%) had fat liquefaction, and two (6.7%) complained of paraesthesia. At 1 month follow-up, two (6.7%) patients showed residual veins. None developed DVT or PE. No death cases were reported either. The recurrence rate at 6-month follow-up was 3.3%. However, GSV recanalization was not reported (Figure 9).

Table 6
Complications (N = 30)

	Frequency	Percentage
Induration	6	20
Ecchymosis	4	13.3
Skin Burns	3	10
Incision Infection	0	0
Fat Liquefaction	1	3.3
Paraesthesia	2	6.7
Residual Varicose at 4 weeks	2	6.7
DVT	0	0
Pulmonary Embolism	0	0
Death	0	0

Recurrence	1	3.3
Recanalization of GSV	0	0

Discussion

According to CEAP classification in our study, seven (23.3%) patients were C2, Ten (33.3%) patients were C3, Ten (33.3%) were C4 and three (10%) patients were C5. While the mean pre-procedural CEAP classification in the study of (Karnabatidis et al., 2022) was 3.3 ± 0.72 (median: 3; range: 2–6). Baseline severity of the disease according to CEAP classification was C2: 7.8% (5/64), C3: 64% (41/64), C4 (a–b): 23.5% (15/64), C5: 3.1% (2/64), and C6: 1.6% (1/64). The present study showed that the mean diameter of GSV was 7.82 ± 1.56 mm (range, 6 – 15). The mean reflux time was 2.8 ± 1.04 seconds (range, 0.7 – 4). Twenty-one (70%) patients had two or less perforators, while nine (30%) patients had more than two perforators. Our results were supported by the study of (Subwongcharoen & Chitwiset, 2014) as they reported that the mean diameter of GSV was 9.5+1.1 mm.

The current study showed that as regard Procedure Outcomes, The mean procedure time was 40.5 ± 14.6 minutes (range, 30 – 50). The power was adjusted at 50 watts. The mean time for ambulation postoperatively was 2.4 ± 1.8 hours, ranging from 2 to 3 hours. The mean duration for hospital stay was 0.5 ± 0.35 days (range, 0.3 – 1). The mean postoperative VAS for pain was 2±1 (range, 1 – 4). The mean time for ulcer healing was 3.67 ± 1.3 weeks, ranging from 2 to 5 weeks. That procedure outcomes were very close to the the study of (Subwongcharoen & Chitwiset, 2014) as the procedure time was 35 ± 15 minutes (range, 25 – 45). The power was adjusted at 50 watts. The mean time for ambulation postoperatively was 2 ± 1 hours, ranging from 2 to 3 hours. The mean duration for hospital stay was 1 ± 0.35 days (range, 1 – 2). The mean postoperative VAS for pain was 1.5±1 (range, 1 – 4). The mean time for ulcer healing was 3 ± 1 week, ranging from 2 to 5 weeks.

In the study in our hands, as regard preintervention values of venous clinical severity score (VCSS) and Aberdeen varicose vein questionnaire (AVVQ) and follow-up values at 1 and 6 months; The mean preintervention VCSS was 5.6 ± 1.3. After one month, the VCSS improved to 2.1 ± 0.6. At 6-month follow-up, the mean score was 1.2 ± 0.3. A statistically significant improvement was observed in VCSS at different follow-up intervals (Repeated Measure ANOVA, $P < .05$). The mean preintervention AVVQ was 18.5 ± 4.3. After one month, the VCSS improved to 8.1 ± 2.4. At 6-month follow-up, the mean score was 4.5 ± 1.2. A statistically significant improvement was observed in AVVQ at different follow-up intervals (Repeated Measure ANOVA, $P < .05$). In the study of (Yang et al., 2020), there was the same decrease (improvement) in AVVQ and VCSS scores after operation ($p < .001$), there was no significant difference in AVVQ and VCSS scores at any time point ($p > .05$). The improvement in AVVQ and VCSS scores was still present after 2 years.

Our results showed that as regard complications in our study. Six (20%) patients developed induration, four (13.3%) patients had ecchymosis, three (10%) patients had accidental skin burns, and none developed infection at the puncture site.

One patient (3.3%) had fat liquefaction, and two (6.7%) complained of paraesthesia. At 1 month follow-up, two (6.7%) patients showed residual veins. None developed DVT or PE. No death cases were reported either. The recurrence rate at 6-month follow-up was 3.3%. However, GSV recanalization was not reported. Our results were supported by the study of (Karnabatidis et al., 2022) as they reported that no severe complications were noted, and minimal minor complications occurred (two small puncture-site scars), which auto resolved within 3 months, demonstrating the safety of the device.

Conclusion

The present trial confirmed that Endovenous microwave ablation is highly efficacious .Resulting in significant improvements in the severity of venous disease with lower CEAP values after treatment. What has been shown clearly is that successful treatment of venous insufficiency results in significant Quality of Life (QoL) improvements. Complications Of Endovenous ablation includes the following: pain, abscess, seroma, hyperpigmentation, and burn of the skin shown and explained in details in our study. There are no reports of direct comparisons of EMA and other Endovenous ablation techniques. However, the published data slightly higher occlusion rates for microwave ablation. However, long-term follow-up and quantification of 5- to 10 year recurrence rates will be important. Conclusively, according to this single-center, single-arm, prospective study, endovenous microwave ablation of the great saphenous vein, for the treatment of symptomatic lower limb varicose veins, was safe and effective, resulting in very low complication rates, without any incidences of DVT or persistent paresthesia, low levels of post-procedural pain, and extremely satisfactory radiological and clinical mid-term outcomes. Larger, comparative studies are required to verify these results

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